



Failure to submit such an amendment requested by the Agency will prompt a review of the application which may result in rescission of this tentative approval letter.

Any significant change in the conditions outlined in this abbreviated application requires Agency approval before the change may be made effective.

Prior to the issuance of a final approval letter by the Agency your product is not to be deemed approved for marketing under 21 U.S.C. 355 and not to be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list, published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to April 22, 1997, you should amend your application accordingly.

At the time you submit any amendments, you should contact Mr. Timothy W. Ames, Project Manager, at (301) 594-0305, for further instructions.

The introduction or delivery for introduction into interstate commerce of the drug before the effective approval date is prohibited under 21 U.S.C. 311(d).

Sincerely yours,

Roger L. Williams, M.D.  
Deputy Center Director for  
Pharmaceutical Science  
Center for Drug Evaluation and Research